SECTION 2 – 510(k) SUMMARY

Trident Anchor

JUN - 9 2006

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767
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Name of Medical Device	Classification Name: Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners Common/Usual Name: Bone Anchor Proprietary Name: Trident Anchor
Substantial Equivalence	Trident Anchor is substantially equivalent to: ROC EZ Fastener (K970089 & K971922); the Arthrex Pushlock Anchor (K051219) and the ArthroCare Opus Magnum Implant (K042914).
Device Classification	This device carries an FDA product code MBI and HWC, and is classified as Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fasteners under 21 CFR 888.3040.
Device Description	The Trident Anchor System includes the Trident Anchor, which will be presented sterile, pre-mounted on an inserter shaft w/anvil with or without a threader tab and suture. The System will be deployed with the use of a reusable Deployment Gun. The Anchor could be provided with a variety of #2 suture options.

Indications for Use	Trident Anchor is indicated for use in the following: **Shoulder:** Rotator Cuff Repair, Biceps Tenodesis, **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; Joint Capsule Closure **Elbow:** Biceps Tendon Reattachment
Safety and Performance	Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices. Based on the indications for use, technological characteristics, and comparison to predicate devices, the Trident Anchor has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2006

DePuy Mitek
a Johnson & Johnson Co.
% Ms. Ruth C. Forstadt
Project Management Lead, Regulatory
Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K060914
Trade/Device Name: Trident Anchor
Regulation Code: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulation Class: II
Product Code: HWC, MBI
Dated: April 3, 2006
Received: April 4, 2006

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060914

Device Name: Trident Anchor

Trident Anchor is indicated for use in the following:

Shoulder: Rotor Cuff Repair, Biceps Tenodesis
Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis; Joint Capsule Closure
Elbow: Biceps Tendon Reattachment

Prescription Use ___√__ OR Over-the -Counter Use __No
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number K060914